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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,945	03/27/2001	Hsuan-Yin Lan-Hargest	12938-002001	5280

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/03/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,945

Applicant(s)

LAN-HARGEST ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 3,8,9,11,13-16,19-39 and 47-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,10,12,17,18,40-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The subject matters directed to the elected species are allowable in view of the decision by Board of Patent Appeals and Interferences. Note the elected invention is “method of inhibiting histone deacetylase in cells, thereby treating a disorder,” applicant further elected 7-phenyl-2,4,6-hepta-trienoylhydroxamic acid as the elected compound, and cancer as the elected disorder. The search and examination have been extended to non-elected species, particularly, to other compounds encompassed with the scope of claim 1.

The claims have been examined insofar as they read on elected invention, elected disorder, and the searched compound. Therefore, claims 3, 8, 9, 11, 13-16, 19-39, 47-53, are withdrawn from consideration as they are drawn to no-elected invention, or to species have not been searched.

Claim Objections

1. Claims 40 and 41 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Particularly, claims 40 and 41 recited compounds with oxo substituent in L or CO as Y2, (e.g., potassium 2-oxo-6-phenyl-3,5-hexadienoate), such compounds are out of the scope of claim 1 since claim 1 does not include compounds, of which L is substituted with oxo, or Y2 is -CO-.

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Claim Rejections 35 U.S.C. 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 4-7, 10, 12, 17, 18, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richon et al.

4. Note claim 43 constructively makes the claims herein read on *in vitro*. Richon et al. teaches that certain hydroxamic acids, which are within the scope of the general formula defined in claim 1, inhibit histone deacetylase, induce terminal differentiation and or apoptosis in various transformed cells, see the abstract. With respect to the compounds, note compound 7 in table 1 of Richon et al. is within the scope of the formula (I), wherein L is a straight C5 hydrocarbon chain, Y1 is a bond and Y2 is $-NR^c-CO-NR^d-$, (or considering Y2 is a bond and L is interrupted by $-NR^c-CO-NR^d-$), and A is halo substituted aryl. Further, the references teaches that compounds variation of L, Y1, Y2 and A, as suggested herein, still provide the activity. The variations include unsaturated carbon bond in L. see the table 1 in Richon et al.

5. Richon does not teach the steps of determining the level of acetylated histone as recited herein in the claims.

However, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to judge the efficacy of the treatment by

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determining whether the level of acetylated histone in the treated cells is higher than in untreated cells since it is known the treatment is realized by inhibiting histone deacetylase.

6. Claim 42, 44-46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richon et al. as discussed above, and in further view of Marks et al. (IDS).

7. Richon et al. do not teach expressly the in vivo application of the histone deacetylation inhibitors, or thereby treating cancers.

8. However, Marks et al. teaches that hydroxamic acids encompassed those disclosed herein, as histone deacetylase inhibitors, are potentially effective agent for cancer therapy, see the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use compound 7 of Richon et al for in vivo application, or for treating cancers, since hydroxamic acids, as histone deacetylase inhibitors, are known to be useful for cancer therapy.

9. Claims 1, 2, 4-7, 10, 12, 17, 18, 40-46 rejected under 35 U.S.C. 103(a) as being unpatentable over Breslow et al. (US 6,511,990).

10. Breslow et al. teaches that hydroxamic acids with various substituents are useful as histone deacetylase inhibitors. Breslow et al. further provide a method of using the hydroxamic acids, or their homologs, or analogs for treating various cancers. See, particularly, columns 4-5, and columns 11-12. Breslow et al. does not specifically recite the compounds recited herein. However, it is noted the hydroxamic acids disclosed by Breslow et al. include those with substituted and unsubstituted aryl attached to the hydroxamic acid moiety through a C3-11

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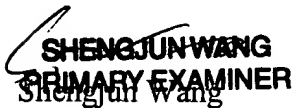
carbon chain (column 4, line 55 bridge column 5, line 10 and column 11, lines 61-67).

Therefore, the compounds disclosed by Breslow et al. overlapped with the compounds herein employed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571)272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.


SHENGJUN WANG
PRIMARY EXAMINER
Shengjun Wang

May 5, 2004


BRUCE KISLIUK, DIRECTOR
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